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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT		ATTORNEY DOCKET NO.
08/480,850	06/07/95	PELLETT	P	1414.657

18M1/1114

DAVID G PERRYMAN
NEEDLE AND ROSENBERG
SUITE 1200 THE CANDLER BUILDING
127 PEACHTREE STREET NE
ATLANTA GA 30303-1811

EXAMINER	
LEE, D	
ART UNIT	PAPER NUMBER
1815	

DATE MAILED: 11/14/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/480,850	Applicant(s) Philip E. Pellett
	Examiner Danny Lee	Group Art Unit 1815

☒ Responsive to communication(s) filed on *paper no. 6 filed 8/5/96*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *7, 8, and 16* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *7, 8, and 16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1815**.

1. Receipt is acknowledged of applicants' amendment in Paper No. 6 wherein claims 7-8 are amended and claim 16 are presented. Accordingly, claims 7-8, 16 are under consideration in the present application.

2. Rejection of claims 7-8 under 35 U.S.C. 112, second paragraph in paper No. 5 is withdrawn in view of the declaration and amendments in paper No. 6.

3. Claim 16 is objected to because of the following informalities: Claim 16 contain a typographical error: line 2, "hespes". Appropriate correction is required.

4. Rejection of claims 7-8 and newly presented claim 16 under 35 U.S.C. 102(b) as anticipated or 35 U.S.C. 103 as being obvious over either Lee et al. (Applicant's AA1) or Lee et al. (Applicant's AW) in paper No. 5 **is maintained** for the reasons presented at page 6 of the office action (4/30/96).

Applicant's arguments filed 8/5/96 (paper No. 6) have been considered are not deemed persuasive. Applicant argues that the novel plasmid pAcDSM, is engineered to receive the foreign gene precisely at the translation initiation codon of the polyhedron gene, without missing any nucleotide present in the native 5' nontranslated leader sequence is noted. Applicant's argument is not supported by the as-filed specification or evidence. The claims are drawn toward a purified herpes simplex virus gG1 and/or gG-2 antigens and not toward the baculoviral expression system. Applicant's claims constitute a product-by-process type claims and the burden is upon applicant to demonstrate the patentable distinction between the material, structural and functional characteristics of the claimed composition and the compositions of the prior art. In conclusion, applicant have not provided any evidence to the contrary wether the proteins of the prior art are different or may in fact be the same proteins as those claimed by applicant.

5. Rejection of claims 7-8 and newly presented claim 16 under 35 U.S.C. § 103 as being unpatentable over Lee et al. (AA1) or Lee et al. (AW) in view of Luckow et al. (AO) or Matsuura et al. (AP) in paper No. 5 **is maintained** for the reasons presented at page 6-8 of the office action (4/30/96).

Applicant's arguments filed 8/5/96 (paper No. 6) have been considered are not deemed persuasive. Applicant argues that the novel plasmid pAcDSM, is engineered to receive the foreign gene precisely at the translation initiation codon of the polyhedron gene, without missing any nucleotide present in the native 5' nontranslated leader sequence is noted, but applicant has failed

to provide evidence tosupport this assertion . The claims are drawn to a purified herpes simplex virus gG1 and/or gG-2 antigens and not toward the baculoviral expression system. Applicant's claims constitute a product-by-process type claims and the burden is upon applicant to demonstrate the distinction between the material, structural and functional characteristics of the claimed composition and the compositions of the prior art. Applicant argues that the protein made by the expression system of Sanchez-Martinez and Pellett (Exhibit 1), may differ from the art because of the differences of the transfer vector (page 233, column 2). Sanchez-Martinez et al teaches that "human serum specimen reacted most strongly with the 128K, and the monoclonal antibody (H1206) with the 118K...in asmuch as other human serum specimens reacted most strongly with 118K". Also from figure 2A on page 233, one cannot conclude that the recombinant protein made is different from the prior art if monoclonal antibodies are used to purify the proteins as disclosed on page 7 of the specification. Applicant is correct in indicating the difference in the recombinant made protein and those of the prior art if human sera are used in the purification process.

Lee et al (AA1) and Lee et al (AW) both teaches monoclonal antibodies H1206, H1379 and a detection assay. The assay has the sensitivity, specificity and reproducibility for the measurement of HSV-2 and HSV-1 antibodies in seroepidemiological studies (abstract). Applicant on page 7 of the specification teaches the use of antibodies to gG-1 (H1379) and gG-2 (H1206) to purify applicant's recombinant proteins. These monoclonal antibodies appear to be the same monoclonal antibodies used in the prior art.

In conclusion, applicants have not provided any evidence to support a patentable distinction between the proteins of the prior art and those claimed by applicants.

No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 located in Crystal Mall 1. The Fax number for Art Unit 1813 is (703) 305-7939. All Group 1800 Fax machines will be available to receive

transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Danny Lee whose telephone number is (703) 305-7245. The Examiner can normally be reached on Monday-Tuesday from 8:00 AM-6:30 PM, (EST)and Thursday-Friday from 8:00 AM-6:30 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marian Knode, can be reached at (703) 308-4311.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Danny Lee

November 8, 1996

Marian C. Knode

MARIAN C. KNODE
SUPERVISORY PATENT EXAMINER
GROUP 1800